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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/714,200

11/14/2003

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EXAMINER

WERNER, JONATHAN S

ART UNIT

PAPER NUMBER

3732

MAIL DATE

DELIVERY MODE

08/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary

Application No.

10/714,200

Applicant(s)

IHDE, STEFAN

Examiner

Jonathan Werner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-60 and 67-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-60 and 67-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
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DETAILED ACTION

1. This action is in response to Applicant's amendment received 3/26/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 58-60, 69-71 and 75-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regard to claim 58, it is not entirely clear from the specification what the claimed "inner aspect" and "peripheral aspect" are. Similarly, in claim 75, Examiner cannot distinguish from the specification what the claimed "leading portion" and "trailing portion" of the base are. As to claim 77, it is not apparent what the claimed "waist" portion is from the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 53, 58-60, 69-71, 73 and 75-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner does not understand

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what "first side" the claimed ridges can be located on since the claimed "one of said heights" can be located on either the top surface, bottom surface, or both surfaces of the base as outlined in claim 42. Further, Examiner does not understand what the claimed "first direction" represents and how a ridge can be concave to only one direction. Additionally, Applicant claims the ridges are rectilinear on a base side opposite from the first side, but again, it is not clear what side that could be, especially if both sides of the base have varying heights that comprise ridges. With respect to claim 58, it is not clear what Applicant means by "an inner aspect," i.e. whether Applicant is referring to the central portion of the surface of the base or the actual inside portion of the base. For the purpose of examination, Examiner will understand the claim language based on the former interpretation. With respect to claim 73, it is not clear how the claimed "through holes" can define a bar. As to claim 75, it is not clear what the claimed "leading portion" and "trailing portion" of the base are. For the purpose of examination, said portions will be interpreted as the intermediate regions of the base separating the inner region and the peripheral region. As to claim 76, Examiner does not understand what variations, and of which width, Applicant is referring to, since previous claim 75 describes two separate widths of the base portion. As to claim 77, it is not fully understood what the claimed "waist" represents. For the purpose of examination, Examiner will interpret the "waist" as if it is part of the intermediate region of the base which separates the inner region and the peripheral region. In claim 78, it is not entirely clear what the "leading portion" is and its relation to the peripheral portion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 42-43, 46-47, 51, 53, 55, 57-59, 67-71, 75-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson (US 6,238,214). In regard to claims 42 and 58, Robinson discloses an osteal implant comprising a shaft (i.e. 11,23) having a longitudinal axis and having a first end and a second end at opposing ends of said longitudinal axis (i.e. see Figures 11 and 13); said first end having a mount for a device (i.e. 17) to be implanted (i.e. see Figures 11 and 17); said second end being terminally attached to a top surface of a base (i.e. 30, Figure 13); said base being substantially planar, rectilinear and orthogonal to said longitudinal axis in at least two non-parallel directions as shown by the embodiments of the base in Figures 12 and 15; at least one of a top surface or a bottom surface of said base having a first height (i.e. 32) at a first radial distance from said longitudinal axis and a second height (i.e. 33) at a second radial distance from said longitudinal axis; said first height being maintained through at least two directions radial to said longitudinal axis (i.e. in directions toward each edge of the base); said second height being maintained through at least two directions radial to said longitudinal axis (i.e. the height of surface element 33 extends along the periphery of the base); and both of said top surface and said bottom surface being disposed for osseointegration (i.e. bone growth surfaces on the base are shown in Figures 12 and

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15). As to claims 43 and 67-68, the first height 33 is representative of a mound with a circular circumference as demonstrated in Figures 13 and 15, and is therefore maintained through an arc that can be 180° between said at least two directions radial to said longitudinal axis. As to claim 46, the second height has a sharp edge along its periphery as shown for example in Figures 13-17. As to claim 47, the base, as shown for example in Figure 13, has a third height located along the incline portion of the center mound, intermediate the top of which defines said first height (32), and the bottom of which defines said second height (33). Consequently, said third height has a different radial distance from said longitudinal axis than either said first height or said second height. In regard to claim 51, said base as shown in Figures 12 and 15 has an outer perimeter which includes at least three substantially straight edges. As to claim 53, as best understood by Examiner, Figure 15 shows a series of curvilinear ridges on the surface of the base at its second height located along its periphery. In regard to claim 55, said second height (33) is at a marginal zone of said base located along a height of a periphery of said base (column 7, line 45). As to claim 57, said marginal zone comprises reentrant angles at each bone-growth region such as those shown on the surface of the base in Figure 15. As to claims 59 and 70, the radial width of the peripheral aspect of the base varies since the base is rectangular per Figure 15 of Robinson, and wherein the peripheral width increases radially along the longer side of the base, and decreases radially along the shorter side of the base. As to claim 69, the first thickness (i.e. 32) is greater than the second thickness (35) as shown in Figure 13. In regard to claim 71, as best understood by Examiner, since the inner aspect includes

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the thickened region 32 and its corresponding mound-shaped incline portion, its radial width varies based on the position of said incline. Furthermore, in claims 75-76, the base as shown in Figure 13 has a leading portion (i.e. left side of mound portion 32) and a trailing portion (i.e. right side of mound portion 32), and wherein variations of the width of said boundary are symmetrical around the base. As to claim 77, the narrower width of said boundary of the inner portion shown in Figure 13 comprises a waist on said trailing portion of said base located at the edge of the mound shaped region. As to claim 78, as best understood by Examiner, the peripheral portion of the base has a leading edge which connects to the inner aspect of the base, and of which is thinner than said inner aspect as shown in Figure 13.

5. Claim 72 is rejected under 35 U.S.C. 102(b) as being anticipated by Albrektsson et al. (WO 01/24737). Albrektsson discloses an osteal implant comprising a shaft (i.e. 3) that is substantially orthogonal to a substantially planar base at one end (i.e. 20), and wherein said shaft and said base comprise a substantially T-shaped implant end portion (see Figure 3), and wherein at least one surface (i.e. 21) of said base having a plurality of crests alternating with a plurality of grooves (i.e. 22), both said crests and said grooves being curvilinear around said shaft through substantially 180° (see Figure 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 44-45, 48, 54, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson in view of Berrang et al. (US 6,516,228). Robinson discloses an osteal implant as previously described in detail above, but fails to show the heights alternate periodically or comprise a spiral. Berrang, however, teaches an osteal implant which can have one or more ridges and grooves that alternate and can be spirally disposed on the base (column 3, lines 41-48). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make the heights alternate periodically or comprise a spiral in order to promote osseointegration with bone of the patient as taught by Berrang.

7. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson in view of Baege et al. (US 5,965,006). Robinson discloses an osteal implant as previously described in detail above, but fails to show at least one of said portions comprises a bowl-like depression. Baege, however, teaches a prosthetic device for implanting in bone which has a portion that comprises bowl-like depressions (Figure 1a). Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to make at least one of the portions of the implant have bowl-like depressions substantially vertical on a base oriented opposite from the direction of insertion in order to provide a sufficient anchoring depth for ingrowing bone matter during osseointegration as taught by Baege.

8. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson. Robinson discloses the osteal implant as previously described but fails to disclose the claimed range of heights. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the heights vary in a range from about 0.05 mm to about 0.25 mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson in view of Karmaker (US 6,186,791). Robinson discloses an osteal implant as previously described, but fails to show the first and second heights comprise barbs oriented to resist extraction of the implant. Karmaker, however, teaches a dental post implant comprised of barbs (Figure 1). Therefore, it would have been obvious to one having ordinary skill in the art to add barbs to the implant portions in order to aid in the retention of the implant in the bone as taught by Karmaker.

10. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson in view of Grafelmann (US 4,538,304). Robinson discloses an osteal implant as previously described but fails to show the width of the peripheral portion or the thickness varies. Grafelmann, however, teaches a prosthetic device for implanting in bone which has a base with a first height (top of Figures 2,4) and a second shorter

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height that is along a portion of a periphery of said base (bottom of Figures 2,4), wherein the thickness of the base varies. Therefore, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to make the thickness of the base vary in order to promote a better retention of the device within the bone and the surrounding body tissue as taught by Grafelmann.

11. Claims 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Streel (US 4,334,757) in view of Berrang (US 6,516,228). In regard to claim 72, Streel discloses an osteal implant comprising a shaft (2), said shaft being substantially orthogonal to a substantially planar base at one end (see Figure 1), and wherein said shaft and said base comprise a substantially T-shaped implant end portion (see Figure 1). Streel fails to show at least one surface of said base having a plurality of crests alternating with a plurality of grooves, both said crests and said grooves being curvilinear around said shaft through substantially 180°. However, Berrang teaches an osteal implant which can have one or more ridges and grooves that alternate and can be spirally disposed (column 3, lines 41-48). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include said plurality of alternating curvilinear crests and groove in order to promote osseointegration with bone of the patient as taught by Berrang. As to claim 73, Streel additionally shows the implant comprises at least two through holes in said base, said through holes defining a bar, said bar running substantially through a center of said base, said bar being attached to said shaft, and said holes defining a base peripheral area (see

especially Figure 2). In regard to claim 74, the peripheral area shown in Figure 2 is substantially rectilinear over about one-half of said base.

Response to Arguments

12. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

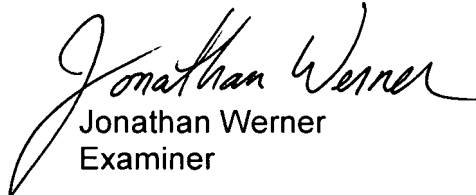
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jonathan Werner
Examiner

6/17/07


MELBA N. BUMGARNER
PRIMARY EXAMINER